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BIOMET

510(k) Summary

Preparation Date: February 5, 2007

MAY - 3 2007

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Tracy Bickel Johnson, RAC

Proprietary Name: 100 kGy E-Poly™ MaxRom™ Acetabular Liners

Common Name: UHMWPE Liners

Classification Name(s):

- LPH- prosthesis, hip, semi-constrained, metal/polymer, porous uncemented (888.3358);
- JDI- prosthesis, hip, semi-constrained, metal/polymer, cemented (888.3350);
- LWJ- prosthesis, hip, semi-constrained, metal/polymer, uncemented (888.3360);
- MAY- prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous cemented, osteophilic finish (888.3353)
- LZO- prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented (888.3353)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: K050327- E-Poly™ (Vitamin E) Acetabular Liners

Device Description: Biomet Manufacturing Corp. is modifying the manufacturing process of ultra-high molecular weight polyethylene (UHMWPE) used in the fabrication of polyethylene acetabular components. The modified manufacturing process results in a higher cross-linked polyethylene. The highly cross-linked UHMWPE is infused with medical grade Vitamin E.

Intended Use:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed total hip arthroplasty.

Cemented and Uncemented Applications

Summary of Technologies: The intended use, indications, contraindications, and design specifications of the subject components remain identical to its predicate counterpart, with the exception of a manufacturing change. The raw material being utilized in the manufacture of both the subject and the predicate devices remains a ultra-high molecular weight polyethylene (UHMWPE) per ASTM F-648. The modifications to the manufacturing process of this polyethylene will be introduced in order to create a higher cross-linked polyethylene. The safety and effectiveness of this cross-linked polyethylene in acetabular applications are adequately supported by the substantial equivalence information, materials data, and testing results provided within this Premarket Notification.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet Manufacturing Corp.
℅ Ms. Tracy Bickel Johnson, RAC
Manager, Regulatory Affairs
P.O. Box 587
Warsaw, Indiana 46581-0587

MAY - 3 2007

Re: K070364
Trade/Device Name: 100kGy E-Poly™ MaxRom™ Acetabular Liners
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JDI, LWJ, LPH, MAY
Dated: April 3, 2007
Received: April 4, 2007

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

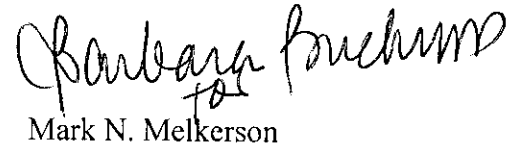
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070364

Device Name: 100kGy E-Poly™ MaxRom™ Acetabular Components

Indications For Use:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2) Rheumatoid arthritis.
3) Correction of functional deformity.
4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5) Revision of previously failed total hip arthroplasty.

Cemented and Uncemented Applications

Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070364